UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

APR 0 3 2019

~~**CONTAINS CONFIDENTIAL BUSINESS INFORMATION**~~

BY EMAIL

OPP Decision Number: 539846
EPA File Symbol: 87394-L
Product Name: Ninja Neem
EPA Receipt Date: March 27, 2018
EPA Company Number: 87394
Company Name: Dyna-Gro

Kimberly Hensley
Senior Regulatory Specialist
Dyna-Gro
2775 Giant Road
Richmond, CA 94806

Dear Ms. Hensley:

The U.S. Environmental Protection Agency (Agency or EPA), Biopesticides and Pollution Prevention Division (BPPD), has completed its preliminary technical screening of your applications pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Because your response to the 10-day deficiency letter dated July 13, 2018 did not correct the failure related to product chemistry and human health data requirements for the end-use product, as detailed below, BPPD has determined that your application did not pass the preliminary technical screening and, therefore, must be rejected.

Specifically, in a letter dated July 13, 2018, sent by email, the EPA notified you of the preliminary technical screening failure for the application (EPA File Symbol 87394-L) and your opportunity to correct your application within 10 business days of the receipt of that notice. You acknowledged receipt of this letter on July 13, 2018 via email. You submitted a response to the 10-day letter on July 26, 2018, within the 10-day period. The screen failures, the information you submitted to cure those deficiencies, and the status of EPA's review of the information, are summarized in full in the attached **Confidential Appendix**.

In the July 13, 2018 10-Day Letter, the Agency identified deficiencies pertaining to the Confidential Statement of Formula (CSF), product chemistry data requirements (Data Guidelines: 880.1200, 830.1700, 830.6313, 830.6315, 830.6317, 830.6320, 830.7000, 830.7050, 830.7300, 830.1700, 830.7220, 830.7520, 830.7550-830.7570), human health data requirements (Data Guidelines: 870.1100,

870.1200, 870.1300, 870.2400, 870.2500, 870.2600, 870.3100, 870.3250, 870.3465, 870.3700, 870.5100, 870.5300, and 870.5375), and nontarget organism toxicology data requirements (Data Guidelines: 850.2100, 850.2200, 850.1075, 850.1010, 850.4100, 850.4150, and 880.4350).

In a response to the EPA's July 13, 2018, letter, you provided an additional transmittal document, cover letter, revised CSF, certification with respect to citation of data form, data matrix, proposed label, and revised product identity and composition (Group A) and physical and chemical properties (Group B) data to address the deficiencies in the 10-Day Letter. Upon review, the EPA has determined that your response to the preliminary technical screening failure letter does not adequately address the following deficiencies: Preliminary Analysis (data requirement 830.1700) - information on impurity profile was not provided, Stability (data requirement 830.6313) - stability information to elevated temperatures and metals/metal ions was not provided, pH (data requirement 830.7000) - the method or source of the pH was not provided, UV/Visible Light Absorption (data requirement 830.7050) - only the absorption value and method (partial response) were submitted. For the Acute Toxicity (data requirements 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600), Bacterial Reverse Mutation test (data requirement 870.5100), and In vitro mammalian cell assay (870.5300 and 870.5375), the bridging argument could not be considered because the given test substance cannot clearly be identified. A summary of the EPA's findings is provided in greater detail in the attached Confidential Appendix.

Any future submissions to the EPA will be considered new applications and subject to the full registration service fees, as well as additional initial content screenings and preliminary technical screenings.

Please note, the response to the deficiencies for the CSF and OCSPP Guideline 880.1200, 830.6315, 830.6317, 830.6320, 830.7300, 830.7100, 830.7220, 830.7520, 830.7550-830.7570, 870.3700, 870.3465, 870.3250, 870.3100, 850.2100, 850.2200, 850.1075, 850.1010, 850.4100, 850.4150, 880.4350 are preliminarily acceptable should you decide to submit those same data in support of a future product application.

If you have questions concerning this letter, please contact Alex Horansky of the Biopesticides and Pollution Prevention Division by telephone at (703) 347-0128 or via email at horansky.alex@epa.gov.

Sincerely,

Richard P. Keigwin, Jr.
Director
Office of Pesticide Programs

Attached: **Confidential Appendix**